510(k) Summary

for

ONTEX SCENTED DIGITAL AND PLASTIC APPLICATOR TAMPONS

1. Submission Sponsor

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3. Date Prepared

13th June 2013

4. Device Identification

Trade/Proprietary Name:	ONTEX SCENTED DIGITAL AND PLASTIC APPLICATOR TAMPONS
Common/Usual Name:	SCENTED MENSTRUAL TAMPONS
Classification Name:	SCENTED OR SCENTED-DEODORIZED MENSTRUAL TAMPON
Classification Regulation:	21 CFR 884.5460
Product Code:	HIL
Device Class:	Class II
Classification Panel:	OBGYN, Obstetrics/Gynecology

5. Legally Marketed Predicate Device(s)

Ontex Unscented Digital and Plastic and Cardboard Applicator Tampons	K122603

6. Device Description

The Scented Tampons are:
1) Scented Digital
2) Scented Plastic Applicator (full size (long) and compact)

They are scented versions because of the presence of a fragrance.

Tampon Type	Applicator Material	Applicator Size	Absorbencies
Roll wadding	n/a, digital	n/a, digital	<6g, 6-9g, 9-12g, 12-15g
W wadding	plastic	Full size (long)	<6g, 6-9g, 9-12g, 12-15
W wadding	plastic	Compact	<6g, 6-9g, 9-12g, 12-15

Both the Applicator and Digital Tampons are inserted into the vagina to absorb menstrual discharge.

These tampons, both the digital types and the applicator types will be provided with 4 absorbencies: light (<6g), regular (6-9g), super (9-12g), and super plus (12-15g).

These tampons are made from viscose material and polymeric overwrap. The withdrawal cord is in polyester and cotton. Applicators are in polyethylene.

Roll-tampon: sheet of absorbent material is rolled and pressed.
W-tampon: sheet of absorbent material is folded and pressed from two sides simultaneously.

Long applicator: inner tube and outer tube are ready to be used immediately.
Compact applicator: inner tube and outer tube are slided into each other telescopically. The inner tube needs to be retracted before usage.

Except for the perfume, the materials used in these tampons are similar to materials of legally marketed tampons.

7. Indication for Use Statement

The Scented Digital and Plastic Applicator Tampons are inserted into the vagina to absorb menstrual discharge.

8. Substantial Equivalence Discussion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A –General Comparison of Characteristics

Manufacturer	ONTEX	ONTEX	SIGNIFICANT DIFFERENCES
Trade Name	SCENTED DIGITAL AND PLASTIC APPLICATOR TAMPONS	UNSCENTED DIGITAL AND PLASTIC AND CARDBOARD APPLICATOR TAMPONS (K122603)	Presence of a fragrance for the scented version.
510(k) Number	Not yet defined	K122603	
Product Code	HIL	HEB	different
Regulation Number	21 CFR PART 884.5460	21 CFR PART 884.5470	different
Regulation Name	Scented or scented-deodorized menstrual tampon	Unscented menstrual tampon	different
Indications for Use	Inserted into the vagina to absorb menstrual discharge	Inserted into the vagina to absorb menstrual discharge	same
Material	Absorbent pledget in viscose, polymeric overwrap, cotton polyester cord. Plastic applicators in polyethylene. Perfume.	Absorbent pledget in viscose, polymeric overwrap, cotton polyester cord. Plastic applicators in polyethylene . Cardboard applicator in paper.	same except perfume and no applicator in cardboard, only plastic.
Tampon Type and Applicator (material and size)	Roll wadding digital W wadding plastic applicator full size (long) and compact	Roll wadding digital W wadding plastic applicator full size (long) and compact	same
Absorbencies	<6g, 6-9g, 9-12g, 12-15g	<6g, 6-9g, 9-12g, 12-15g	same
Sterile	no	no	same
Single-Use	yes	yes	same
Complies with ISO 10993-1	yes	yes	same

Table 5B – Comparison of Characteristics Digital Tampons

Manufacturer	ONTEX	ONTEX	SIGNIFICANT DIFFERENCES
Trade Name	SCENTED DIGITAL AND PLASTIC APPLICATOR TAMPONS	UNSCENTED DIGITAL AND PLASTIC AND CARDBOARD APPLICATOR TAMPONS (K122603)	Presence of a fragrance for the scented version.
Total weight (g)	1.2 – 3.7	1.2 – 3.7	Same
Weight without applicator (g)	NA	NA	NA
Withdrawal cord Length (mm)	145	145	Same
Length with applicator (mm)	NA	NA	NA
Length without applicator (mm)	39 - 49	39 - 49	Same
Diameter with applicator (mm)	NA	NA	NA
Diameter without applicator	10.4 – 14.8	10.4 – 14.8	Same
Pledget	100% viscose	100% viscose	Same
Non-Woven Cover	Polyester/Polyethylene	Polyester/Polyethylene	Same
Withdrawal cord	Polyester/Cotton	Polyester/Cotton	Same
Applicator	NA	NA	NA
Perfume	yes	no	Different

Table 5C – Comparison of Characteristics Applicator Tampons

Manufacturer	ONTEX	ONTEX	SIGNIFICANT DIFFERENCES
Trade Name	SCENTED DIGITAL AND PLASTIC APPLICATOR TAMPONS	UNSCENTED DIGITAL AND PLASTIC AND CARDBOARD APPLICATOR TAMPONS (K122603)	Presence of a fragrance for the scented version.
Total weight (g)	3.6 – 6.4 for compact 3.6 – 8.1 for full size	3.6 – 6.4 for compact 3.6 – 8.1 for full size	Same
Weight without applicator (g)	1.1 – 3.7 for compact 1.2 – 3.8 for full size	1.1 – 3.7 for compact 1.2 – 3.8 for full size	Same
Withdrawal cord Length (mm)	120	120	Same
Length with applicator (mm)	120 for compact 125 for full size	120 for compact 125 for full size	Same
Length without applicator (mm)	40 – 45 for compact 45 for full size	40 - 45 for compact 45 for full size	Same
Diameter with applicator (mm)	13.5 – 18.2 for compact 11.5 – 16.5 for full size	13.5 – 18.2 for compact 11.5 – 16.5 for full size	Same
Diameter without applicator (mm)	11.0 – 15.0 for compact 11.5 – 15.5 for full size	11.0 – 15.0 for compact 11.5 – 15.5 for full size	Same

Manufacturer	ONTEX	ONTEX	SIGNIFICANT DIFFERENCES
Trade Name	SCENTED DIGITAL AND PLASTIC APPLICATOR TAMPONS	UNSCENTED DIGITAL AND PLASTIC AND CARDBOARD APPLICATOR TAMPONS (K122603)	Presence of a fragrance for the scented version.
Pledget	100% viscose	100% viscose	Same
Non-woven cover	Polypropylene/Polyethylene	Polypropylene/Polyethylene	Same
Withdrawal cord	Polyester/Cotton	Polyester/Cotton	Same
Applicator	Plastic polyethylene	Plastic applicator in polyethylene, Cardboard applicator in paper.	Same but no applicator in paper
Perfume	yes	no	Different

9. Non-Clinical Performance Data

Biocompatibility and microbiology testing have been performed to support substantial equivalence:

- The ONTEX SCENTED TAMPONS were tested as non-cytotoxic, non-irritant, with no terminal or gross observations in the reproductive tracts of any of the animals, with no exhibiting toxic signs, and with a negligible dermal response. They did not indicate a potential for dermal irritation or allergic contact sensitization.

- The test tampon does not enhance the growth of Staphylococcus aureus. It does not increase the production of Toxic Shock Syndrome Toxin-1 (TSST-1). It had no effect on culture pH. The test tampon does not alter the growth of normal vaginal microflora.

As part of demonstrating safety and effectiveness of ONTEX SCENTED TAMPONS and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, ONTEX completed a number of tests. The SCENTED TAMPONS meet all the requirements for biocompatibility and microbiology and ONTEX confirms that the output meets the design inputs and specifications. The SCENTED TAMPONS passed all testing stated above as shown by the acceptable results obtained.

The SCENTED TAMPONS comply with the applicable voluntary standards for biocompatibility. The device passed all the testing in accordance with national and international standards.

10. Statement of Substantial Equivalence

It can be shown in this 510(k) submission that the difference between the SCENTED TAMPON and the predicate device do not raise any questions regarding its safety and effectiveness.

Design, principals of operation, performance characteristics and intended use between the SCENTED TAMPON and the predicate device are identical. The sole difference is the

presence of perfume for the SCENTED TAMPON. Biocompatibility and microbiological studies demonstrate that the SCENTED TAMPON is substantially equivalent to the relevant aspects of the predicate device in terms of biocompatibility, microbiological and safety . The SCENTED TAMPON, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 10, 2014

ONTEX BVBA
% Rachel Paul
Senior Consultant, QA/RA
Emergo Europe Consulting
Prinsessegracht 20
The Hague 2514AP
Netherlands

Re: K132208
Trade/Device Name: ONTEX SCENTED DIGITAL AND PLASTIC APPLICATOR TAMPONS
Regulation Number: 21 CFR§ 884.5460
Regulation Name: Scented or scented deodorized menstrual tampon
Regulatory Class: II
Product Code: HIL
Dated: March 13, 2014
Received: March 14, 2014

Dear Rachel Paul,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132208

Device Name
ONTEX SCENTED DIGITAL AND PLASTIC APPLICATOR TAMPONS

Indications for Use *(Describe)*
The Scented Digital and Plastic Applicator Tampons are inserted into the vagina to absorb menstrual discharge.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Herbert P. Lerner -S
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